

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
NO. 5:15-CV-634-FL

AVUTOX,LLC,

Plaintiff,

v.

SYLVIA MATTHEWS BURWELL,
in her official capacity as Secretary
of Health and Human Services,

Defendant.

)
)
)
)
)
)
)
)
)
)
)

**MEMORANDUM &
RECOMMENDATION**

This matter is before the court on Defendant's motion to dismiss for lack of subject matter jurisdiction and failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) [DE #14]. Plaintiff has responded, and Defendant has replied. Where this matter has been referred to the undersigned and the parties have not consented to the jurisdiction of the magistrate judge, Defendant's motion is undertaken pursuant to 28 U.S.C. § 636(b)(1)(B) for memorandum and recommendation. For the reasons stated below, it is recommended that Defendant's motion to dismiss be granted.

BACKGROUND

AvuTox, LLC ("AvuTox" or "Plaintiff") is a clinical laboratory that conducts urine drug testing. (Am. Compl. [DE #13] ¶ 7.) Plaintiff provides these services to, among others, beneficiaries of Medicare. (*Id.* ¶ 10.) Medicare is a federal medical

insurance program for the aged and disabled that is governed by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et. seq.*, and is administered by the Secretary of Health and Human Services (“Secretary” or “Defendant”). (*Id.* ¶ 12.)

Plaintiff receives payment for its services to Medicare beneficiaries by submitting claims to Defendant via the Centers for Medicare & Medicaid Services (“CMS”). (*Id.* ¶ 10.) CMS, through third-party contractors, periodically audits claims and recoups money for payments issued if it determines that the services rendered were not medically necessary. (*Id.* ¶¶ 14-15.) If a service provider such as AvuTox is dissatisfied with CMS’ decision that services were not medically necessary, then it may pursue review through a four-step, administrative review process. *See Cumberland County Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 53-54 (4th Cir. 2016) (describing the administrative review process in detail). If the timing deadlines of this review process are not met, then a service provider can “escalate” the process by requesting review at the next step, including review of the final agency decision in federal district court. *Id.* Step three of this process, at issue here, includes a de novo hearing before an Administrative Law Judge (“ALJ”). *Id.*

From fiscal year 2011 through fiscal year 2013, the number of administrative appeals of CMS decisions increased approximately 545%. *See American Hosp. Ass’n v. Burwell*, 812 F.3d 183, 187 (D.C. Cir. 2016). A lack of resources available to adjudicate the appeals has resulted in a backlog of more than 800,000 appeals. With current ALJ staffing levels, it is estimated that it may take as long as ten years to obtain a decision following a hearing before an ALJ. *Id.*

In June 2014, CMS, through its third-party contractor, determined that Medicare had overpaid Plaintiff by approximately \$3.2 million. (Am. Compl. [DE #13] ¶ 45.) Between July and November 2014, Plaintiff initiated review through the first two steps of the administrative review process. (*Id.* ¶¶ 47-52.) Plaintiff was dissatisfied with the decisions at these levels of administrative review and in March 2015 requested a hearing before an ALJ. (*Id.* ¶ 60.) In September 2015, several months after the statutorily imposed ninety-day deadline for an ALJ review hearing, Defendant informed Plaintiff that the hearing before an ALJ would not be scheduled for another 24 to 28 months. (*Id.* ¶ 65.) Plaintiff contests Defendant's recoupment of more than \$3.2 million during the pendency of its appeals. (*Id.* ¶ 64.)

Plaintiff's complaint stems from the failure of Defendant to comply strictly with the third step in this administrative review process, *viz.* that Defendant has failed to conduct an administrative hearing before an ALJ within ninety days after Plaintiff requested such review. Plaintiff seeks (1) a writ of mandamus directing Defendant to comply strictly with the deadline for the administrative review process set forth in 42 U.S.C. § 1395ff(d)(1)(A); and (2) an order directing Defendant to repay the money recouped from Plaintiff and to comply strictly with the deadlines for the administrative review process; or, in the alternative, (3) a declaratory judgment that the court will sit as a court of original jurisdiction rather than a court of appellate jurisdiction if it is determined that Defendant cannot comply strictly with the deadlines of the administrative review process.

DISCUSSION

I. Motion to Dismiss

A. Standard of Review

1. 12(b)(1) Motion

A motion to dismiss under Rule 12(b)(1) of the Federal Rules of Civil Procedure challenges subject matter jurisdiction. The plaintiff bears the burden to establish subject matter jurisdiction. “When a defendant challenges subject matter jurisdiction pursuant to Rule 12(b)(1), ‘the district court is to regard the pleadings as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment.’” *Evans v. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999). If the material jurisdictional facts are not in dispute, and the moving party is entitled to judgment as a matter of law, then the court should grant the Rule 12(b)(1) motion to dismiss. *See id.*

2. Rule 12(b)(6) Motion

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides for dismissal of a complaint or any claims contained therein that fail to state a claim upon which relief can be granted. The intent of the rule is to test the sufficiency of a complaint. *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). The court assumes the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *Revene v. Charles*

Cnty. Comm'rs, 882 F.2d 870, 872 (4th Cir.1989) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

In order to survive a 12(b)(6) motion to dismiss, a complaint must allege facts that raise a right to relief above the speculative level. *Twombly*, 550 U.S. at 544. A complaint need not contain detailed factual allegations, but it must give a defendant fair notice of what the claim is and the grounds upon which it rests. *Id.* at 555. A “formulaic recitation of the elements of a cause of action will not do.” *Id.* “While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations,” which are sufficient to raise a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Facial plausibility is more than “a sheer possibility that a defendant has acted unlawfully.” *Id.* at 678. It requires the plaintiff to articulate facts “that allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

B. Writ of Mandamus

Plaintiff seeks a writ of mandamus and contends that it can satisfy the requirements for mandamus jurisdiction. “Mandamus is a ‘drastic’ remedy that must be reserved for ‘extraordinary situations’ involving the performance of official acts or duties.” *Cumberland*, 816 F.3d at 52 (citations omitted). “[T]he common-law writ of mandamus, as codified in 28 U.S.C. § 1361, is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty.” *Ivanchenko v. Burwell*, No. 1:16CV9056,

2016 WL 6995570, at *4 (N.D. Ill. Nov. 30, 2016) (quoting *Heckler v. Ringer*, 466 U.S. 602, 616 (1984)). A party seeking a writ of mandamus must demonstrate that:

(1) he has a clear and indisputable right to the relief sought; (2) the responding party has a clear duty to do the specific act requested; (3) the act requested is an official act or duty; (4) there are no other adequate means to attain the relief he desires; and (5) the issuance of the writ will effect right and justice in the circumstances.

U.S. ex rel. Rahman v. Oncology Associates, P.C., 198 F.3d 502, 511 (4th Cir. 1999)).

The Fourth Circuit Court of Appeals addressed a similar request in *Cumberland County Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, *pet. reh'g and reh'g en banc denied*, No. 15-1393, ECF 43 (4th Cir. May 3, 2016). There, as in this case, the plaintiff sought a writ of mandamus to compel Defendant to comply strictly with the administrative review process for Medicare payment recoupments. *Id.* at 52. The Fourth Circuit held that the Medicare Act does not create a “right to go to court to enforce the 90-day deadline,” but rather gives “the healthcare provider a choice of either waiting for the ALJ hearing beyond the 90-day deadline or continuing within the administrative process by escalation to the next level of review.” *Id.* at 55. The Fourth Circuit acknowledged that the Medicare Act gives parties such as Plaintiff “the clear and indisputable right to this administrative process,” but held that it does not provide such parties “a clear and indisputable right to adjudication of its appeals before an ALJ within 90 days.” *Id.*

Plaintiff contends that the Fourth Circuit’s analysis is inapplicable here because *Cumberland* failed to address the argument that Defendant’s actions (or lack thereof) violate clear Congressional intent. (Pl.’s Resp. Def.’s Mot. Dismiss [DE #16])

at 12-15.) The Fourth Circuit, however, found that “[t]here is no evidence that Congress ever entertained” the proposition that a court would order the relief requested by Plaintiff. *Cumberland*, 816 F.3d at 54 (“[T]he Hospital System would have a court order the Secretary to address its claims without escalation, to the detriment of all other appeals then pending. The precedent established by this judicial intrusion would surely invite every other delayed claimant into the courts There is no evidence that Congress ever entertained such an idea.”). Contrary to Plaintiff’s argument, the Fourth Circuit specifically considered Congressional intent in *Cumberland*, noting that “Congress anticipated that the 90-day deadline might not be met and provided its chosen remedy” – escalation of administrative and judicial review. *Id.* at 55. In short, the Fourth Circuit considered and rejected Plaintiff’s argument.

C. Due Process Claim

Plaintiff further contends that Defendant’s failure to comply strictly with the deadlines of the administrative review process violates its right to procedural due process. (Am. Compl. [DE #13] ¶¶ 89-110.) Defendant counters that, pursuant to 42 U.S.C. § 405(h), Plaintiff must exhaust available administrative remedies prior to filing suit in federal court. (Def.’s Reply Mem. Supp. Mot. Dismiss Pl.’s Am. Compl. [DE #17] at 5.) Plaintiff concedes this but argues that the court should waive the exhaustion requirement. (Pl.’s Resp. Def.’s Mot. Dismiss Pl.’s Compl. [DE #16] at 19-20.)

Section 405(h) of Title 42 bars a party from bringing an action for claims arising under the Medicare Act against the United States or one of its employees pursuant to federal question jurisdiction without first exhausting administrative review. The Fourth Circuit has acknowledged, however, that “[t]here are several exceptions to the requirement that parties exhaust administrative remedies before seeking refuge in federal courts. These include those instances where (1) the dispute is a matter of statutory construction; (2) the utilization of administrative procedures would cause irreparable injury; and (3) the resort to administrative procedures would be futile.” *McDonald v. Centra, Inc.*, 946 F.2d 1059, 1063 (4th Cir. 1991).

Here, Plaintiff’s argument is bolstered by two facts: that *Cumberland* did not address a Due Process claim and that Plaintiff can make a colorable showing that it satisfies an exception to the exhaustion requirement.

First, *Cumberland* addressed a nearly identical plaintiff’s claim for a writ of mandamus and a declaratory judgment against Defendant. The Fourth Circuit did not consider the argument that Defendant’s failure to comply with the administrative review process deadlines at issue violates Due Process because the *Cumberland* plaintiff did not advance such a claim.

Second, Plaintiff has a somewhat compelling argument that it satisfies all three exceptions to the administrative exhaustion requirement. As evidenced by the Fourth Circuit’s analysis in *Cumberland*, the core issue is whether Congress intended the ninety-day deadline for review before an ALJ to be understood strictly, or whether the statute’s provisions for bypassing certain levels of administrative review imply

that Congress did not intend the deadline to be understood strictly. *Cumberland*, 816 F.3d at 52-55 (analyzing whether the timing deadline of § 1395ff(d) must be understood as mandatory or directory). In a nearly identical case, the D.C. Circuit Court of Appeals reached the opposite conclusion from *Cumberland*. See *American Hosp. Ass’n*, 812 F.3d at 191 (undertaking a similar analysis as to the mandatory or directory nature of the statutory language and concluding that “nothing suggests that Congress intended escalation to serve as an adequate or exclusive remedy where, as here, a systemic failure causes virtually all appeals to be decided well after the statutory deadlines”). Here, the dispute is not only a matter of statutory construction, but is a matter of statutory construction concerning the very administrative procedures Plaintiff is required to exhaust.

Plaintiff contends that Defendant’s recoupment of more than \$3.2 million puts its very existence at risk. (Am. Compl. [DE #13] ¶ 106.) Defendant counters that Plaintiff still has appropriate administrative remedies available and would be further along in this administrative review process had it scheduled the ALJ review hearing when it was advised of the delay of such hearings. (Def.’s Reply Mem. Supp. Mot. Dismiss Pl.’s Am. Compl. [DE #17] at 5-6.) Allowing Defendant’s recoupment of \$3.2 million while requiring Plaintiff to wait two years to schedule a hearing (Am. Compl. ¶ 65) that may not take place for ten years could realistically cause irreparable harm to Plaintiff. See *Cumberland*, 816 F.3d at 49 (“[A]s of February 2014, the Secretary had 480,000 appeals awaiting assignment to an ALJ, and the Secretary conceded in

her brief that the number had by then climbed to more than 800,000 appeals, creating a ten-year backlog.”).

This ten-year backlog also undergirds Plaintiff’s argument that exhaustion of its administrative remedies is futile. (Pl.’s Resp. Def.’s Mot. Dismiss [DE #16] at 20 (“Requiring AvuTox to exhaust its claim has no effect on its due process claim other than to exacerbate the harm, as exhaustion likely requires yet another round of agency review.”)); *see also Cumberland*, 816 F.3d at 49 (ten-year backlog). While the undersigned sympathizes with Plaintiff, this argument is at odds with the Fourth Circuit’s reasoning in *Cumberland*.

Despite the fact that the *Cumberland* court did not directly address a Due Process claim, it did consider the underlying issues that give rise to Plaintiff’s Due Process claim. First, while the matter at issue involves a question of statutory construction, the Fourth Circuit has construed the statute, albeit in a way that dissatisfies Plaintiff. The Fourth Circuit’s statutory construction is clear and binding on this court. Second, the Fourth Circuit went to great lengths to explain that the existence of the escalation provision – the provision that allows an appellant to bypass certain levels of administrative review – affords a party such as Plaintiff the ability to bypass the administrative review process and “proceed to court . . . within a relatively expeditious time frame.” *Cumberland*, 816 F.3d at 55. This undermines Plaintiff’s arguments that exhausting the administrative review process would be futile and cause irreparable harm, as Plaintiff can elect to speed up the review process if it so chooses.

Moreover, Plaintiff's Due Process claim cannot withstand a Rule 12(b)(6) motion to dismiss in light of the Fourth Circuit's holding that "the Medicare Act establishes a multilevel, coherent regulatory scheme which authorizes a healthcare provider to bypass levels of review . . . and to create a record that it can ultimately use for judicial review." *Id.* at 56. *Cumberland* forecloses Plaintiff's contentions that the administrative review process creates a constitutionally deficient system with which to create an appellate record.

D. Declaratory Relief

Plaintiff requests that the court order declaratory relief stating that it will sit as a court of original, rather than appellate, jurisdiction if Defendant cannot comply strictly with the deadlines of the administrative review process. The *Cumberland* court rejected a similar claim and emphasized that the Declaratory Judgment Act does not create "substantive rights." *Id.* at 57 (quoting *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849 (2014)). To provide Plaintiff the declaratory relief it seeks would effectively grant it relief on its substantive mandamus and Due Process claims. Accordingly, Plaintiff's claim for a declaratory judgment should be dismissed.

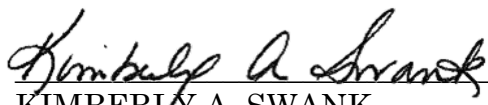
CONCLUSION

For the foregoing reasons, it is RECOMMENDED that Defendant's motion to dismiss [DE #14] be GRANTED and that Plaintiff's claims be DISMISSED for lack of subject matter jurisdiction or for failure to state a claim upon which relief can be granted.

IT IS DIRECTED that a copy of this Memorandum and Recommendation be served on each of the parties or, if represented, their counsel. Each party shall have until **February 7, 2017**, to file written objections to the Memorandum and Recommendation. The presiding district judge must conduct his or her own review (that is, make a de novo determination) of those portions of the Memorandum and Recommendation to which objection is properly made and may accept, reject, or modify the determinations in the Memorandum and Recommendation; receive further evidence; or return the matter to the magistrate judge with instructions. *See, e.g.*, 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3); Local Civ. R. 1.1 (permitting modification of deadlines specified in local rules), 72.4(b), E.D.N.C.

A party that does not file written objections to the Memorandum and Recommendation by the foregoing deadline will be giving up the right to review of the Memorandum and Recommendation by the presiding district judge as described above, and the presiding district judge may enter an order or judgment based on the Memorandum and Recommendation without such review. In addition, a party's failure to file written objections by the foregoing deadline may bar the party from appealing to the Court of Appeals from an order or judgment of the presiding district judge based on the Memorandum and Recommendation. *See Wright v. Collins*, 766 F.2d 841, 846-47 (4th Cir. 1985).

This 24th day of January 2017.


KIMBERLY A. SWANK
United States Magistrate Judge